NOVA SOUTHEASTERN UNIVERSITY

Nova Southeastern University
Standard Operating Procedure for GCP

Title: Research Material Confidentiality		Version # 1
SOP Number: OCR-CON-001	**Effective Date: August 2013**	**Page 1 of 4**

PURPOSE: The relationship between the sponsor and the Center/College is based on the trust that proprietary information disclosed to the Center/College will only be used as necessary to conduct the study. Situations arise, however, when the information needs to be disclosed by the Center/College to a third-party for reasons that may or may not be related to the conduct of the study.

POLICIES:

1. Prior to the beginning of a study, it is customary that an agreement addressing confidentiality of the study supplies be signed between the Center/College and the Sponsor. This is known as a Confidentiality Agreement (CA), Non-Disclosure Agreement (NDA), Confidential Disclosure Agreement (CDA) or some variant thereof.
2. Information covered in this policy is any item containing the following:
   2.1. Sponsor's Name
   2.2. Protocol (including the title and/or number)
   2.3. Informed Consent Form
   2.4. Information of the investigational product (including it's name and supporting documentation such as an Investigator's Brochure or other non-public documentation)
   2.5. Any other information given under the auspices of confidentiality
3. In the absence of a Confidentiality Agreement or in the presence of a more lenient one, the Center/College shall at a minimum:
   3.1. Only discuss the study with the following:
      3.1.1. Sponsor company
      3.1.2. Fellow Employees on a need-to-know basis
      3.1.3. Representatives of the IRB
      3.1.4. Representatives of the FDA, OHRP or other regulating entity
   3.2. Not use the information for purposes other than the intent to conduct the study (i.e. investment/in licensing recommendations, research &

development decisions, and interviews with reporters/financial analysts etc).

Procedure for Obtaining Confidentiality Agreements

1. Sponsor contacts university personnel or principal investigator to evaluate interest in research protocol.
2. Submit proposed contract in Microsoft word document to the OCR to forward to the Assistant Vice President Research and Technology Transfer
3. Assistant Vice President Research and Technology Transfer will do one the following:
   3.1. Submit to Sponsor a previously agreed contract that would govern the release (i.e. a "Global CDA")
   3.2. Submit to sponsor requested changes to the CDA
   3.3. Approve the CDA
4. University personnel, including the principal investigator, should not sign a CDA before it is approved by Assistant Vice President for Research and Technology Transfer.
5. NSU personnel should maintain in good faith any information submitted to Center/College in conjunction with the CDA (i.e. Protocol Summaries) with the expectation that the CDA will be signed

Procedure for Release of Information to Third Parties (Attorney)

1. Review the Confidentiality Agreement and other written instructions from the sponsor. Usually this will allow for disclosure to:
   1.1. CRO
   1.2. IRB
   1.3. FDA, OHRP or other governing authority
   1.4. Other entities directly involved with the conduct or approval of the study (i.e. medical executive boards, pharmacy committees etc.).
2. If disclosure is required pursuant to a court order, the sponsor should be notified as soon as possible to allow for them to utilize their own legal resources to prevent the disclosure if they deem appropriate.
3. Any other requests for disclosures (reporters, physicians not involved in the study) should be directed to the sponsor for disposition. If the sponsor opts for us to disclose the information, this will be obtained in writing prior to disclosure.

(Publication/Presentation of Study Results (Review by Attorney and Vice President Research and Technology Transfer)

PURPOSE: Publications/presentations should be factual in data content as well as adequately describe the conduct of the study (including who and to what degree one participated). Study publications/presentations should also be respectful of sponsor/subject confidentiality.

POLICIES:

1. Any intent to publish any results should first be addressed in the CDA and Clinical Trial Agreement with the sponsor (if a sponsored study).
2. The content should be altogether in conformance with the most recent revision of the International Committee of Medical Journal Editors "*Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication*".
3. Data referenced in the content should only be in aggregate form and not reference any individual subjects without their prior written consent.
4. The content of the publication should be a consensus between the Center/College, the Vice President Research and Technology Transfer and the Sponsor (if a Sponsor funded study).
5. The study should be registered on *ClinicalTrals.Gov*

Procedure to Accept Authorship Credit

1. CRITERIA:
   1.1. Authorship credit shall be based on ALL of the below criteria.
      1.1.1. substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
      1.1.2. drafting the article or revising it critically for important intellectual content; and
      1.1.3. Final approval of the version to be published.
   1.2. Authorship permission shall expressly not be granted for the following:
      1.2.1. Solely from the acquisition of funding, collection of data, or general supervision of the research group
      1.2.2. A document that was substantially written by (or by an agent of) the sponsor without input from the researcher (i.e. "ghost written").
2. Submit draft to Vice President Research and Technology Transfer (who will also handle any other corporate approvals) along with list of intended journals/trade association.

3. If selected to be published/presented, the Vice President Research and Technology Transfer should be notified of the manner of disclosure.

Procedure to Publish/Present Study Data Independently

1. Review the Confidentiality Agreement, the Clinical Trial Agreement and any other relevant documents to obtain the limits of publication rights.
2. Review publication standards of intended journals/trade association prior to drafting content.
3. Ensure study is registered on ***ClinicalTrials.Gov***
4. Submit draft to Vice President Research and Technology Transfer (who will also handle any other corporate approvals) along with list of intended journals/trade association.
5. If the research is sponsored by an external agency, once approved by the Vice President Research and Technology Transfer, the draft should be sent to the sponsor. The Vice President Research and Technology Transfer must review any proposed modifications by sponsor.
6. Submit to prospective journals/trade association. The Vice President Research and Technology Transfer must review any proposed modifications by editor.
7. If selected, the Vice President Research and Technology Transfer should be notified of the intent to publish/present.
8. Additional copies of the journals/poster/slides should be requested for potential distribution internally and externally.